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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,726	02/04/2004	Eugene Brown	WYE-032	6144

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EXAMINER	
HUMPHREY, DAVID HAROLD	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,726	BROWN ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a method comprising detecting an expression profile of at least one gene in a biological sample and comparing to a reference expression profile, wherein one gene is differentially expressed in at least two types of cancer cells as compared to corresponding cancer-free cells, classified in class 435, subclass 5.

II. Claim 9, drawn to a method comprising detecting in a biological sample the level of T cells that are activated by one or more polypeptides, classified in class 435, subclass 372.3.

III. Claims 10 and 11 in part, drawn to a pharmaceutical composition comprising at a pharmaceutical carrier and a polypeptide encoded by a gene which is overexpressed in at least two types of cancer cells, classified in class 530, subclass 300, for example. Claims 10 and 11 will be examined with the instant group to the extent that the composition comprises a carrier and a polypeptide.

IV. Claims 10 and 11 in part, drawn to a pharmaceutical composition comprising at a pharmaceutical carrier and a polynucleotide encoding a polypeptide which is overexpressed in at least two types of cancer cells, classified in class 536, subclass 23.72. Claims 10 and 11 will be examined with the instant group to the

extent that the composition comprises a carrier and a polynucleotide.

V. Claim 12 in part, drawn to a method of administering a polypeptide, classified in class 424, subclass 184.1. Claim 12 will be examined with the instant group to the extent that a polypeptide is administered.

VI. Claim 12, drawn to a method of administering a nucleic acid, classified in class 435, subclass 287.2. Claim 12 will be examined with the instant group to the extent that a polynucleotide is administered.

VII. Claims 13 and 14 in part, and claim 16, drawn to a pharmaceutical composition comprising an agent capable of modulating the expression of a gene, classified in class 536, subclass 24.5. Claims 13 and 14 will be examined with the instant group to the extent that the composition comprises an agent capable of modulating the expression of a gene.

VIII. Claims 13 and 14, drawn to a pharmaceutical composition comprising an agent capable of modulating the activity of a polypeptide, classified in class 435, subclass 69.2, for example. Claims 13 and 14 will be examined with the instant group to the extent that the composition comprises an agent capable of modulating the expression of a polypeptide.

IX. Claim 13 in part, drawn to a pharmaceutical composition comprising a T cell, classified in class 435, subclass 343.2. Claim 13 will be examined with the instant group to the extent that the composition comprises a T cell.

X. Claim 15 in part, drawn to a method comprising administering a composition comprising an agent capable of modulating the expression of a gene in a subject with cancer, classified in class 424, subclass 138.1. Claim 15 will be examined with the instant group to the extent that the composition modulates the expression of a gene.

XI. Claim 15 in part, drawn to a method comprising administering a composition comprising an agent capable of modulating the activity of a polypeptide in a subject with cancer, classified in class 435, subclass 7.23. Claim 15 will be examined with the instant group to the extent that the composition modulates the activity of a polypeptide.

XII. Claim 16, drawn to a pharmaceutical composition, comprising siRNA sense or antisense sequence selected from Table 4, classified in class 536, subclass 24.5.

XIII. Claim 17, drawn to a nucleic acid array, classified in class 536, subclass 23.1.

XIV. Claim 18 in part, drawn to polypeptide array, classified in class 530, subclass 806. Claim 18 will be examined with the instant group to the extent that the array is a polypeptide array.

XV. Claim 18 in part, drawn to an antibody array, classified in class 530, subclass 387.9. Claim 18 will be examined with the instant group to the extent that the array is a antibody array.

XVI. Claim 19, drawn to a kit comprising a polynucleotide probe capable of binding to any one sequence of SEQ ID NOs: 1-44, classified in class 536, subclass 24.32. Claim 19 will be examined with the instant group to the extent that the kit contains a polynucleotide probe.

XVII. Claim 19, drawn to a kit comprising an antibody capable of binding to any one sequence of SEQ ID NOs: 45-88, classified in class 424, subclass 130.1. Claim 19 will be examined with the instant group to the extent that the kit contains a antibody probe.

XVIII. Claim 20, drawn to a method for identifying an agent capable of modulating the activity of a gene, classified in class 435, subclass 455, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different

products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Groups III, IV, VII, VIII, IX, XII, XIII, XIV, XV, XVI, and XVII, are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the polypeptide of Invention III is separate and distinct from the nucleotide of Invention IV. Proteins and nucleic acids have substantially different physical, chemical, structural and functional properties. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo. And while the nucleic acids encode the polypeptides, deoxyribonucleic acids are unbranched polymers composed of four subunits whereas the polypeptides are a linear order of amino acid residues.

The products of Inventions VII, VIII, and IX are separate and distinct. Invention VII is drawn to an agent that modulates the expression of a gene whereas Invention VIII is drawn to an agent that modulates the activity of a polypeptide. Invention IX is drawn to a composition comprising T cells. The products of Inventions VII, VIII, and IX have distinct modes of action and function and are therefore patentably distinct.

The products of Inventions XII, XIII, XIV, and XV, are separate and distinct. These inventions are composed of arrays consisting of nucleic acids, polypeptides, and antibodies, respectively. As mentioned above, nucleic acids are structurally and functionally distinct from polypeptides. Although the proteins and antibodies are related due to the necessary stearic complementarity, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be

used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition or in assays for the identification of agonists or antagonists of the protein.

The products of Inventions XVI and XVII are separate and distinct. Invention XVI is drawn to a kit comprising a polynucleotide probe whereas Invention XVII is drawn to a kit comprising an antibody. The polynucleic acid of Group XVI, and the antibody of Group XVII are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis while the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening and the antibody can be used to immunopurify the antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions XVI and XVII are patentably distinct.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: the methods have separate and distinct method objectives, method parameters and steps, and utilize patentably distinct reagents.

The methods of Inventions I, II, V, VI, X, XI, XVIII, differ in the method objectives, method steps and parameters and in the reagents used. Invention I is drawn to a method of detecting expression profiles whereas Invention II relates to a method of

detecting T cells. Inventions V and VI are drawn to methods of administering a polypeptide and a nucleic acid, respectively. The administration of polypeptides and nucleic acids require separate and distinct reagents and routes of administration. Invention X is drawn to a method of administering an agent that modulates the expression of a gene whereas Invention XI recites a method of administering an agent that modulates the activity of a polypeptide. Therefore, these methods require different modes of action and an agent that modulates the expression of a gene may not necessarily alter the activity of a polypeptide. Invention XVIII is drawn to a method of screening an agent capable of modulating the activity of a gene which is involves utilizing a candidate agent which is not required for methods I, II, V, VI, X, or XI.

The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I, II, V, VI, X, XI, and XVIII, are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions III and II, III and V, III and XVIII, IV and VI, VII and X, VIII and XI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group III can also be used to identify binding partners. The polynucleotide of Group IV can also be used to synthesize

protein. The agent capable of modulating the expression of a gene of Group VII can be used for in vitro transcription assays. The agent capable of modulating protein activity of Group VIII can be used for enzyme activity assays.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

REQUIREMENT FOR FURTHER RESTRICTION

3. If Invention I, III, VI, VII, X, XIII, or XVI, is elected, further restriction is required. Claims 4, 11, 12, 14, 15, 17, and 19, are drawn to claims reciting different combinations of individual nucleotide sequences. Applicant is required to select a particular specific

combination of one or more sequences (not to exceed 10 sequences) from SEQ ID NOs: 1-44 for examination. **THIS IS NOT AN ELECTION OF SPECIES.**

The different sequences of SEQ ID NOs: 1-44 are patentably distinct because they are unique structures composed of different nucleic acid sequences. The search of any particular SEQ ID NO is not coextensive with the search of any other different SEQ ID NOEITHER one specific SEQ ID NO. OR one specific combination of SEQ ID NO and a reference against one sequence is not necessarily a reference against any other sequence.

4. If Invention II, IV, V, VIII, IX, XI, XIV, XV, XVII or XVIII, is elected, further restriction is required. Claims 9, 11, 12, 13, 14, 15, 18, 19, and 20, are drawn to claims reciting different combinations of individual polypeptide sequences. Applicant is required to select a particular specific combination of one or more sequences (not to exceed 10 sequences) from SEQ ID NOs: 45-88 for examination. **THIS IS NOT AN ELECTION OF SPECIES.**

The different sequences of SEQ ID NOs: 45-88 are patentably distinct because they are unique structures composed of different amino acid sequences. The search of any particular SEQ ID NO is not coextensive with the search of any other different SEQ ID NOEITHER one specific SEQ ID NO. OR one specific combination of SEQ ID NO and a reference against one sequence is not necessarily a reference against any other sequence.

5. If Invention XII, is elected, further restriction is required. Claim 16 is drawn to claims reciting different combinations of individual siRNA sense or antisense sequences (SEQ ID NOs: 89-48,640; see Table 4 in the specification, pages 46-48). Applicant is required to select a particular specific combination of one or more sequences (not to exceed 10 sequences) from SEQ ID NOs: 89-48,640 for examination. **THIS IS NOT AN ELECTION OF SPECIES.**

The different sequences of SEQ ID NOs: 89-48,640 are patentably distinct because they are unique structures composed of different siRNA sequences. The search of any particular SEQ ID NO is not coextensive with the search of any other different SEQ ID NOEITHER one specific SEQ ID NO. OR one specific combination of SEQ ID NO and a reference against one sequence is not necessarily a reference against any other sequence.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

May 16 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER